REMARKS

Claims 108, 110-114 and 116-119 are currently pending in the application. Claims 112 and 113 are withdrawn from consideration. Claims 108, 110, 111, 114 and 116-119 are under consideration, and stand rejected under 35 U.S.C. § 112, first paragraph based on a number of positions laid out in detail in the 03/17/03 Office Action. Applicant respectfully disagrees with the conclusions set forth in that office action. However, in order to expedite prosecution of a portion of their invention of particular current interest, Applicant has presented a set of more narrowly focused amended claims on pages 3-8 of this paper (See also attached Appendix A).

Specifically, claims 108, 110, 114 and 116 have been amended. Claims 111-113 and 117-119 remain unchanged. Applicant respectfully submits that no new matter is added through the proposed amendment to the claims. Below we address each of the rejections stated in the Office Action as if it were applied to the newly amended claims.

The claim amendments are being made solely to expedite prosecution of the subject matter now claimed, rather than in acquiescence to any positions taken by the Examiner. In fact, Applicant is *not* acquiescing to any of those positions and is submitting the present Amendment without prejudice to the subsequent prosecution of claims to some or all of the subject matter which might be lost by virtue of this paper.

1 **Withdrawn claims**

The Examiner has withdrawn claims 112 and 113 from consideration. Accordingly, the listing of claims submitted herewith identifies these claims as "Withdrawn". However, Applicant notes that claims 112 and 113 had been allowed in the Office Action issued January 15, 2003 (paper No.: 9). It is Applicant's understanding that these claims will be submitted for rejoinder once claims currently under consideration are found allowable.

2. Amendments to the specification:

The Amendments to the specification merely seek to correct obvious errors (*e.g.*, typographical or clerical errors). For example, the proposed amendments to structures at the top

of pages 48 and 58 find support *inter alia* on page 53 (*i.e.*, structure at the top of the page). No new matter is added with this amendment.

3. Amendments to the claims:

The claims have been amended to focus attention on subject matter of particular current interest to Applicant.

For example, claims 108 and 114, as amended, recite protein or peptide as suitable carriers to which compounds of the invention might be attached, either directly or through a cross-linker. Support for this amendment can be found throughout the specification, for example on page 49 lines 5-12 in the recitation that R (*i.e.*, the moiety to which the determinant of claims 108 and 114 may be attached) can be an amino acyl residue of a peptide or protein. Furthermore, claims 110 and 116 has been amended to remove recitation of "lipid" for the carrier. In addition, claims 108, 110, 114 and 116, have been amended to remove the term "M_2 linker", which is rendered unnecessary by inclusion of the linker structure within the claims. Furthermore, claims 108, 110, 114 and 116 have been amended to remove the proviso that "*when R is a ceramide moiety, the set of indices (r, m, n) is not (1, 0, 1)*". Applicant respectfully submits that these amendments do not introduce new matter.

4. Objection to the Amendment "filed July 3, 2002" under 35 U.S.C. § 132

The Examiner objects to the Amendment "filed July 9, 2002" under 35 U.S.C. § 132 because it allegedly introduces new matter into the disclosure. To provide a clear record, the Amendment referred to by the Examiner was filed by Applicant on July 3, 2002 and was received by the USPTO on July 9, 2002. That Amendment was filed with a Certificate of Mailing dated July 3, 2002. Therefore, the Amendment is deemed filed July 3, 2002, even though it was not received by the PTO until July 9, 2003.

A. The Examiner objects to the amendment found at the bottom of page 2 and top of page 4 of the 7/3/03 Amendment because the structure being replaced includes indices "r", "m" and "n" whereas the original structures found on pages 48 and 58 had no such index "n". Applicant notes

the structure at the top of page 4 of the 7/3/03 Amendment does not have indices "r", "m" and "n". Applicant believes that the Examiner in fact meant the structure at the top of page 5 of the 7/3/03 Amendment. In an effort to expedite prosecution, Applicant will address the objection as if it were applied to the amendments made in section 2) page 2 and section 5) page 5 of the 7/3/03 Amendment.

Applicant has canceled the amendments in question, thereby obviating the objection.

B. The Examiner objects to the amendment found in section 3) of page 19 of the 7/3/03 Amendment which replaces an acetyl group with a hydroxyl group. For clarity purposes, Applicant points out that this amendment is on page 3 of the 7/3/03 Amendment.

Applicant submits that the amendment in question merely sought to correct a clerical error, and respectfully points out that specific support for the deacetylated structure can be found, for example, on page 43 lines 15-20 of the specification. No new matter is added with this amendment. Accordingly, Applicant respectfully requests that the stated objection be withdrawn.

C. The Examiner objects to the amendment found in section 4) of page 4 of the 7/3/03 Amendment which replaces a structure bearing a t-butyl group with an open-ended bond, and also replaces a benzoyl group with a hydroxyl group.

Applicant submits that the amendment merely sought to correct a clerical error, and respectfully points out that specific support for the structure lacking the benzoyl group can be found, for example, on page 46 lines 10-15 of the specification. With respect to the "t-butyl structure", Applicant respectfully submits that it does not in fact represent a t-butyl group; rather, it is meant to designate an attachment point, as evidenced by the use of the term "determinant". No new matter is added with this amendment. Accordingly, Applicant respectfully requests that the stated objection be withdrawn.

D. The Examiner objects to the amendment found in section 64) of page 5 of the 7/3/03 Amendment which replaces three benzyl groups and one acetyl group with hydroxyl groups.

Applicant submits that the amendment merely sought to correct a clerical error and respectfully points out that specific support for the structure lacking benzyl and acetyl groups can be found, for example, on page 43 lines 15-20 of the specification. No new matter is added with this amendment. Accordingly, Applicant respectfully requests that the stated objection be withdrawn.

5. Rejections under 35 U.S.C. § 112, first paragraph

Claims 108, 110, 111, 114 and 116-118 are rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner states that the limitation "*when R is a ceramide moiety, the set of indices (r, m, n) is not (1, 0, 1)*" finds no support in the specification. The claims, as amended, do not recite said language. Therefore, the rejection is now moot.

6. Rejections under 35 U.S.C. § 102(b) set forth in paper No.: 9

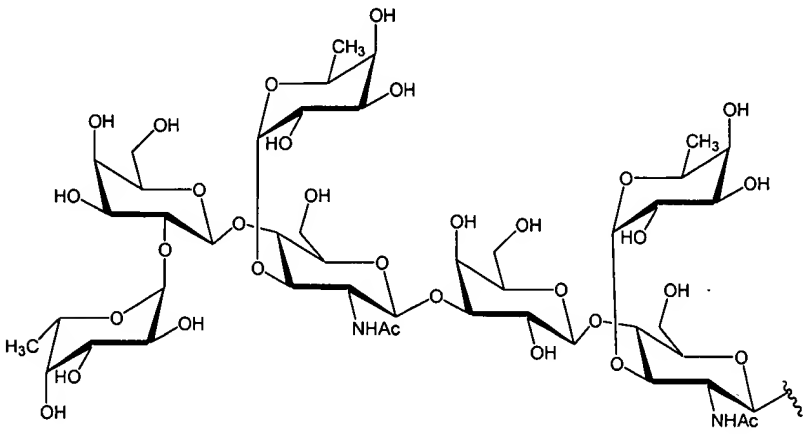
In an effort to expedite prosecution, Applicant hereby addresses the § 102(b) rejections set forth in the Office Action mailed 1/15/03 (Paper No.: 9) to demonstrate that the instant claims satisfy the novelty requirement under 35 U.S.C. § 102(b).

A. 35 U.S.C. § 102(b) rejection over Windmüller *et al.* (Tetrahedron Letters, 1994, Vol. 35, pp. 7927-7930) or Helland *et al.* (Journal of Carbohydrate Chemistry, 1992, Vol. 11, pp. 77-80).

The Examiner stated that Windmüller *et al.* disclose the chemical synthesis of the determinant of claim 110 (citing structure 2c on page 7929), where the set of indices (r, m, n) is (1, 0, 1) and wherein R is a substituted alkyl group. The Examiner also alleged that Helland *et al.* disclose the chemical synthesis of the determinant of claim 110 (citing structure 13 on page 80), where the set of indices (r, m, n) is (1, 0, 1) and wherein R is a substituted alkyl group.

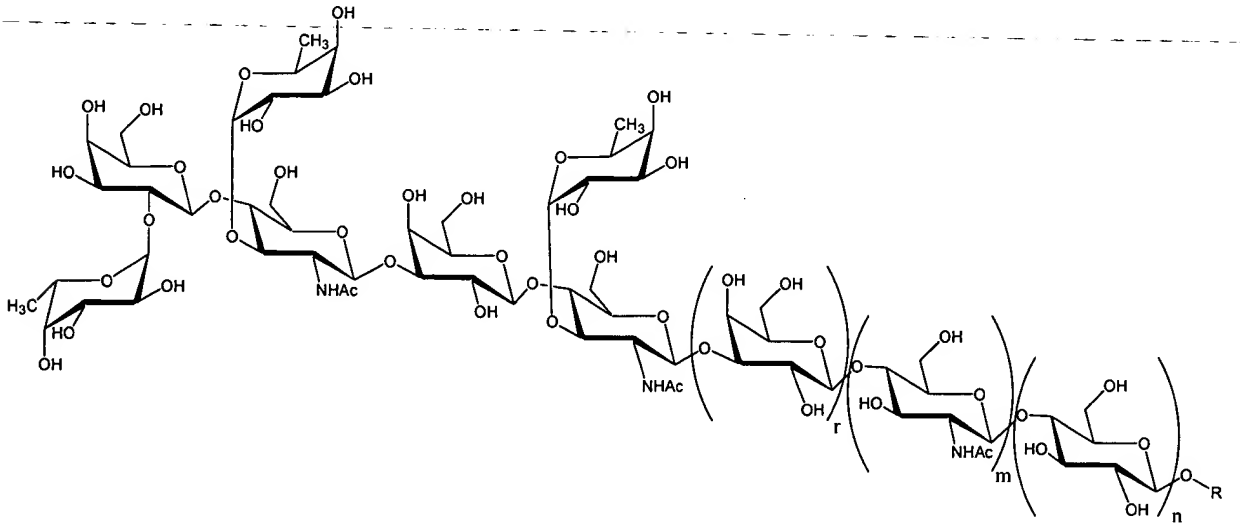
As stated in the Response to Office Action filed March 28, 2003, Applicant assumes that the Examiner meant to compare Helland's structure 13 with the determinant of claim 110 where the set of indices (r, m, n) is (0, 0, 0), not (1, 0, 1).

Claim 108, as amended, is directed to a compound having the determinant:



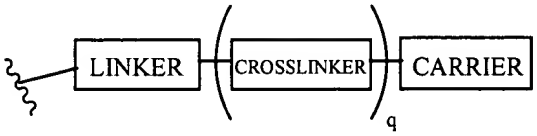
wherein the compound is bound to a suitable carrier protein or peptide. Helland does not teach carbohydrate constructs attached to a carrier protein or peptide. Therefore Helland does not anticipate claim 108. Likewise, Windmüller does not teach compounds having the determinant of claim 108, wherein the compound is bound to a suitable carrier protein or peptide. Therefore Windmüller does not anticipate claim 108.

Claim 110, as amended, is directed to a compound having the structure:



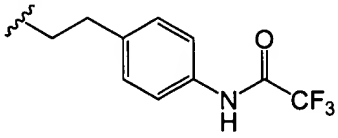
wherein r, m, and n are independently 0, 1, 2 or 3;

R is H, substituted or unsubstituted allyl, an amino acyl moiety, or a moiety having the structure:



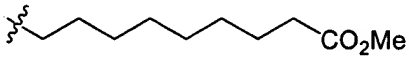
wherein q, the linker, crosslinker and carrier are as defined in claim 110.

The compounds disclosed in the Helland *et al.* reference do not fall within the scope of claim 110. Specifically, with respect to structure 13 on page 80 of the Helland *et al.* reference, the moiety having the structure:



does not fall within the definition of R as set out in claim 110. Therefore Helland does not anticipate claim 110.

Likewise, the compounds disclosed in the Windmüller *et al.* reference do not fall within the scope of claim 110. Specifically, with respect to structure 2c on page 7927 of the Windmüller *et al.* reference, the moiety having the structure:



does not fall within the definition of R as set out in claim 110. Therefore Windmüller does not anticipate claim 110.

Claims 114 and 116, as amended, are directed to compositions comprising an inventive compound and an immunological adjuvant and/or a pharmaceutically acceptable carrier. Neither Helland nor Windmüller teaches compositions comprising an immunological adjuvant and/or a pharmaceutically acceptable carrier. Therefore, the Helland and Windmüller references cannot anticipate claims 114 and 116.

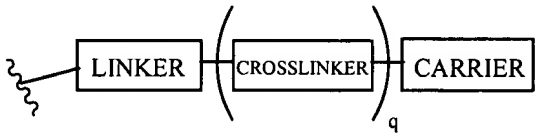
In view of the remarks above, Applicant respectfully submits that the Windmüller *et al.* and/or the Helland *et al.* reference(s) do not anticipate the instant claims.

B. 35 U.S.C. § 102(b) rejection over Nudelman *et al.* (The Journal of Biological Chemistry, 1986, Vol. 261, pp. 11247-11253).

The Examiner stated that Nudelman *et al.* disclose the isolation and structural determination of compounds having the determinant of claims 108 and/or 110, wherein the set of indices (r, m, n) is (1, 0, 1), the determinant is bound to a –linker-(crosslinker)$_q$-carrier moiety, wherein the linker is $-(CH_2)_s-$ wherein s is 2, q is 0, and the carrier is a lipid (citing the phytosphingosines referred to in figure 4B on page 11251 of the Nudelman *et al.* reference).

Claim 108, as amended, encompasses compounds bound to a carrier protein or peptide. The compounds disclosed in the Nudelman *et al.* reference do not fall within the scope of claim 108. As the Examiner pointed out, phytosphingosines are lipids, not proteins or peptides. Accordingly, Nudelman cannot anticipate claim 108.

Likewise, claim 110 does not encompass compounds disclosed in the Nudelman *et al.* reference. Specifically, Nudelman *et al* disclose compounds where the carbohydrate determinant is attached to a phytosphingosine moiety (*i.e.*, lipid), which is different from R being H, substituted or unsubstituted allyl, an amino acyl moiety, or a moiety having the structure:



;

where q, the linker and the crosslinker are as defined in claim 110, and the carrier is a protein or peptide. Therefore, Nudelman cannot anticipate claim 110.

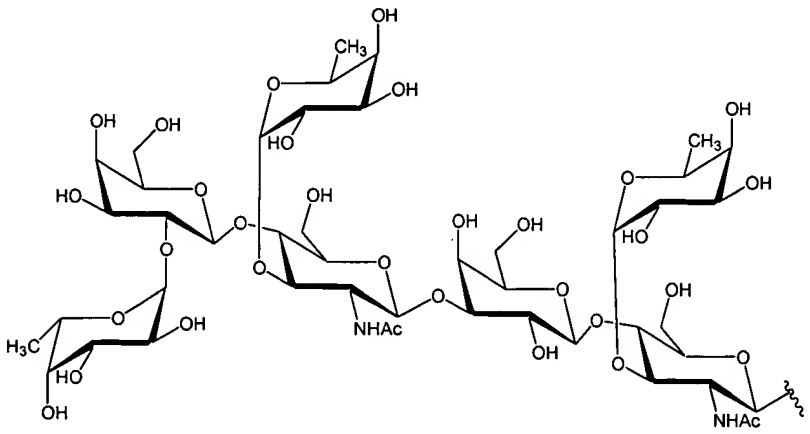
Claims 114 and 116, as amended, are directed to compositions comprising an inventive compound and an immunological adjuvant and/or a pharmaceutically acceptable carrier. Nudelman does not teach compositions comprising an immunological adjuvant and/or a pharmaceutically acceptable carrier. Therefore, the Nudelman reference cannot anticipate claims 114 and 116.

In view of the remarks above, Applicant respectfully submits that the Nudelman *et al.* reference(s) does not anticipate the instant claims.

C. 35 U.S.C. § 102(b) rejection over Kaizu *et al.* (The Journal of Biological Chemistry, 1986, Vol. 261, pp. 11254-11258).

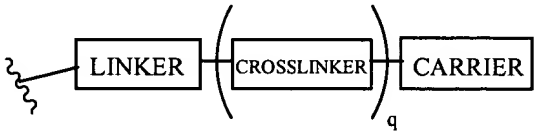
The Examiner stated that Kaizu *et al.* teach a composition of Le^y trifucosylceramide and salmonella Minnesota cells (citing the paragraph entitled "Materials and Methods on page 11254 of the Kaizu *et al.* reference).

Claims 108 and 114, as amended, are directed to a compound having the determinant:



wherein the compound is bound to a suitable carrier protein or peptide, and compositions thereof, respectively. Ceramide not being a protein or peptide, Le^y trifucosylceramide does not fall within the scope of these claims. Therefore Kaizu cannot anticipate claims 108 and 114, and claims dependent thereon (*e.g.*, claims 117-119).

Similarly, Le^y trifucosylceramide does not fall within the scope of claim 110 or 116, since ceramide is neither H, substituted nor unsubstituted alkyl, aryl or allyl, an amino acyl moiety, nor a moiety having the structure:



wherein q, the linker and crosslinker are as defined in claims 110 and 116, and the carrier is a protein or peptide. Therefore, Kaizu cannot anticipate claims 110 and 116, and claims dependent thereon (*e.g.*, claims 117-119).

In view of the remarks above, Applicant respectfully submits that the Kaizu *et al.* reference(s) does not anticipate the instant claims.

Applicant thanks Examiner Canella for her time and consideration. If a telephone conversation would help clarify any issues, or help expedite prosecution of this case, Applicant invites the Examiner to contact the undersigned at (617) 248-5150.

Although it is believed that there is no fee associated with this Amendment, if Applicant is mistaken, please charge any fees to our Deposit Account No.: 03-1721.

Respectfully submitted,

Dated: October 16, 2003

Nadège M. Lagneau, Ph.D.
Reg. No.: 51,908

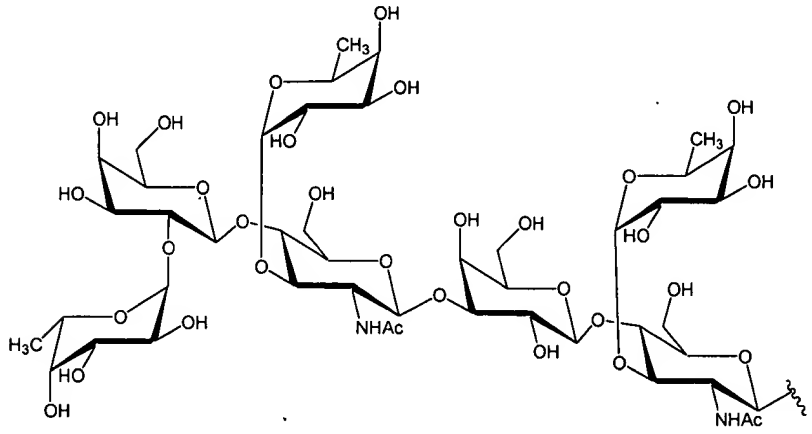
PATENT GROUP
CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, MA 02109
(617) 248-5150

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313
on October 16, 2003
Kathy Hart Gagnon

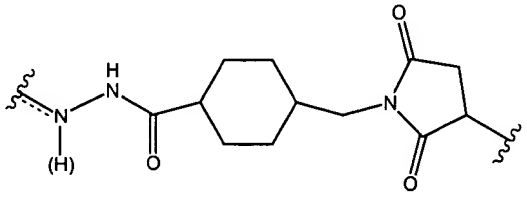
- APPENDIX A -

CLAIMS AS PENDING AFTER ENTRANCE OF THE PRESENT AMENDMENT

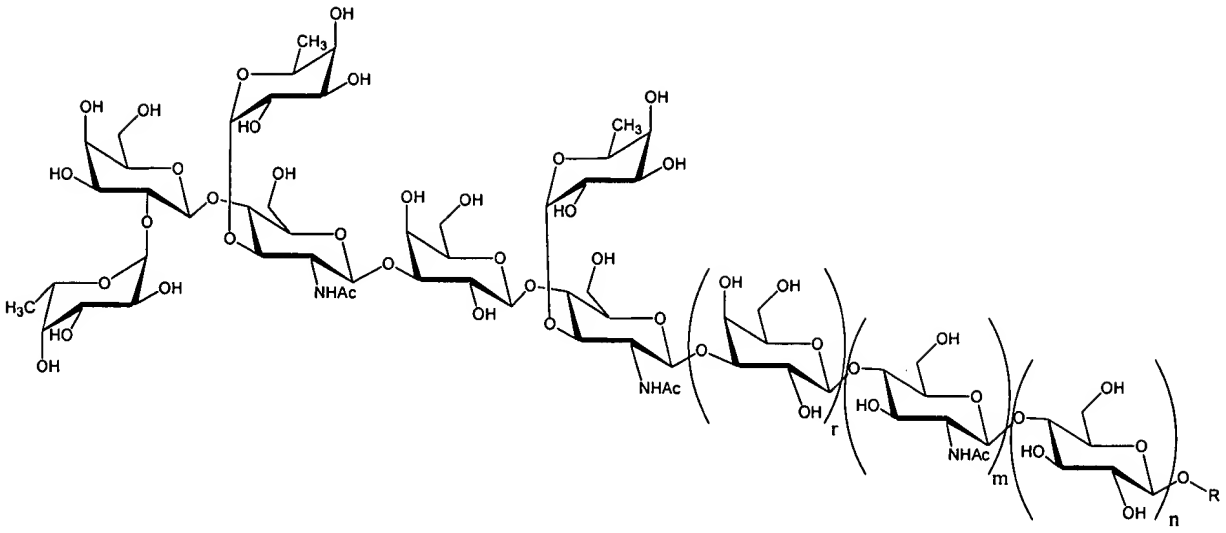
108. A compound which contains a determinant having the structure:



wherein the compound is bound to a suitable carrier protein or peptide, said compound being bound either directly or by a cross-linker selected from the group consisting of a succinimide and a linker having the structure:

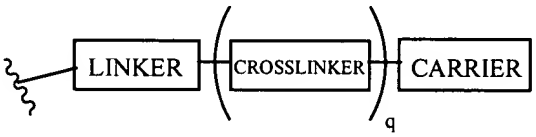


110. A compound having the structure:



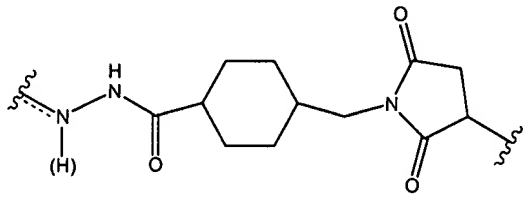
wherein r, m, and n are independently 0, 1, 2 or 3;

R is H, substituted or unsubstituted allyl, an amino acyl moiety, or a moiety having the structure:



wherein the linker is $-(CH_2)_s-CH_2-$ or $-(CH_2)_s-CH=$ where s is an integer between 0 and 8;

the crosslinker is selected from the group consisting of a succinimide and a linker having the structure:



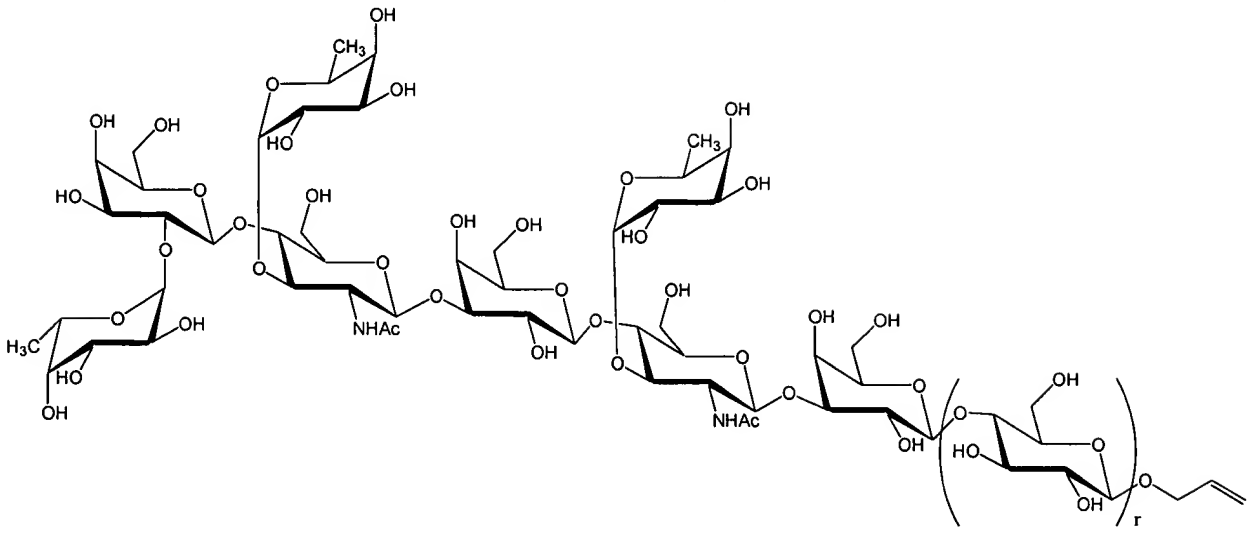
q is 0 or 1; and

the carrier is a protein or peptide, and is optionally chemically modified prior to conjugation with the linker when q is 0, or with the crosslinker when q is 1.

111. The compound of claim 108 or 110 wherein the protein is bovine serum albumin,

polylysine, or keyhole limpet hemocyanin.

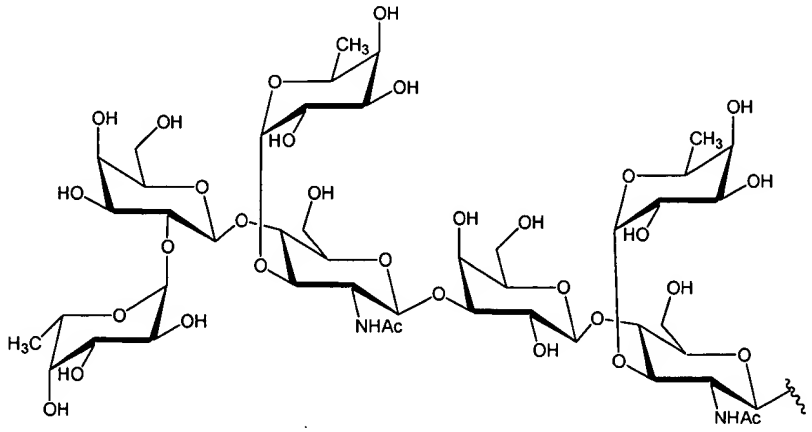
112. A compound having the structure:



wherein r is 0, 1, 2, 3, or 4.

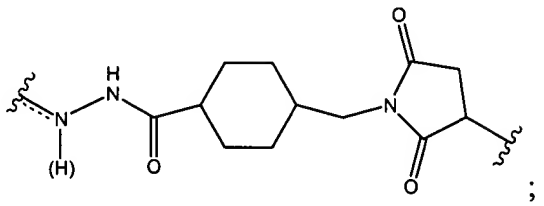
113. The compound of claim 112 wherein r is 1.

114. A composition comprising a compound which contains a determinant having the structure:



wherein the compound is bound to a suitable carrier protein or peptide, said compound

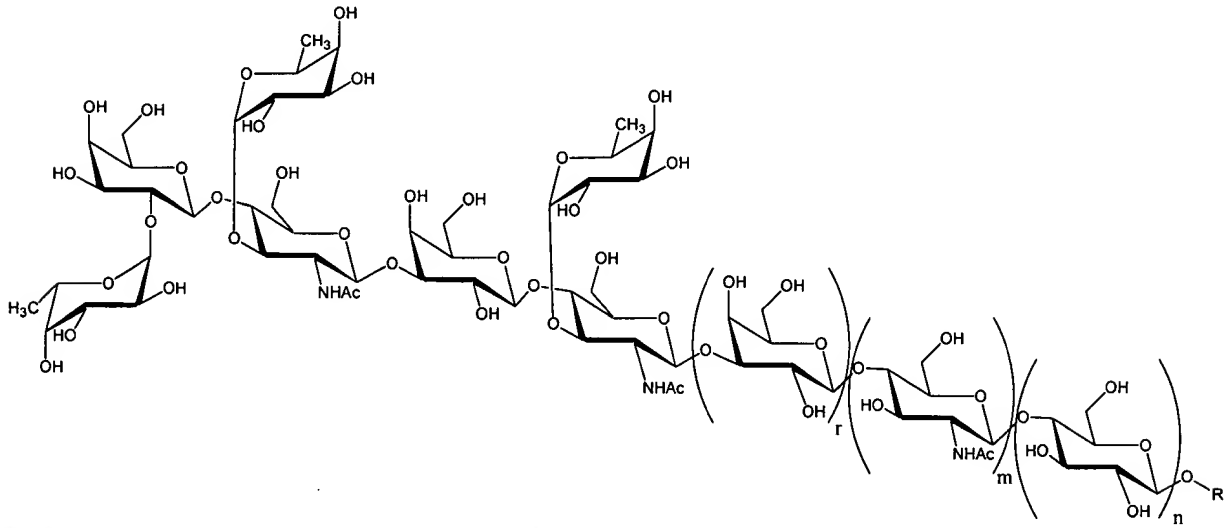
being bound either directly or by a cross-linker selected from the group consisting of a succinimide and a linker having the structure:



;

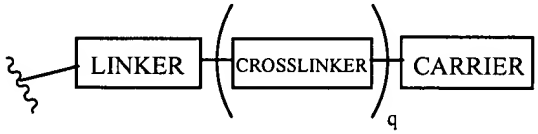
and an immunological adjuvant and/or a pharmaceutically acceptable carrier.

116. A composition comprising a compound having the structure:



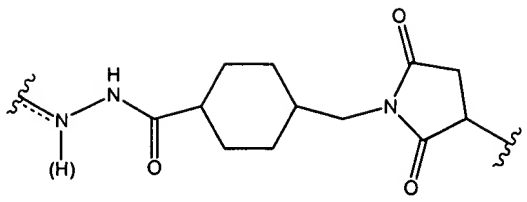
wherein r, m, and n are independently 0, 1, 2 or 3;

R is H, substituted or unsubstituted alkyl, aryl or allyl, an amino acyl moiety, or a moiety having the structure:



wherein the linker is $-(CH_2)_s-CH_2-$ or $-(CH_2)_s-CH=$ where s is an integer between 0 and 8;

the crosslinker is selected from the group consisting of a succinimide and a linker having the structure:



q is 0 or 1; and

the carrier is a protein or peptide and is optionally chemically modified prior to conjugation with the linker when q is 0, or with the crosslinker when q is 1;

and an immunological adjuvant and/or a pharmaceutically acceptable carrier.

117. The composition of claim 114 or 116 wherein the protein is bovine serum albumin, polylysine, or keyhole limpet hemocyanin.

118. The composition of claim 114 or 116 wherein the immunological adjuvant is bacteria or liposomes.

119. The composition of claim 118 wherein the adjuvant is *Salmonella minnesota* cells, bacille Calmette-Guerin or QS21.